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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/848,600	05/03/2001	Peter Watts	WC 111	9982

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EXAMINER
GAMBEL, PHILLIP

ART UNIT	PAPER NUMBER
1644	12

DATE MAILED: 01/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/848600	Applicant(s) WATTS:ET AL
	Examiner GAMBEL	Art Unit 644

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☑ Responsive to communication(s) filed on 10/18/01

2a)☐ This action is **FINAL**. 2b)☑ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☑ Claim(s) _____ is/are pending in the application. 1-5, 7, 9-11

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☑ Claim(s) _____ is/are rejected. 1-5, 7, 9-11

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☑ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☑ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☑ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). 08/776,470

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☐ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☑ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other:

PAPER NO. 14

DETAILED ACTION

1. Upon reconsideration in the interest of compact prosecution and applicant's arguments, filed 10/28/02 (Paper No. 9), the previous Restriction Requirement has been withdrawn.

Accordingly, claims 1-5, 7 and 9-12 are pending and being acted upon presently.

Claims 6 and 8 have been canceled previously.

2. Applicant should amend the first line of the specification to update the status (and relationship) of the U.S. priority documents.

3. Applicant is invited to clarify the priority date of the instant claims. For example, it does not appear that foreign priority United Kingdom 9414966.3, filed 7/26/94 provides sufficient written description for "a drug delivery composition" and for all of the claimed formulation limitations (e.g. 0.2 - 2.0% w/v of ICAM-1 and between about 0.1 and 50% by weight). Therefore, the priority date of the instant claims may be 7/24/95 rather than 7/26/94. If applicant desires priority to 7/26/94; applicant is invited to point out and provide documentary support for the priority of the instant claims. Applicant is reminded that such priority for the instant limitations requires written description and enablement under 35 U.S.C. § 112, first paragraph.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office Action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-5, 7 and 9-12 are rejected under 35 U.S.C. § 103 as being unpatentable over Igari et al. U.S. Patent No. 5,482,706; 1449) AND/OR Greve et al. (U.S. Patent No. 5,589,453; 1449) in view of Wegner et al. (U.S. Patent No. 5,730,983; 1449), Gwaltney et al. (U.S. Patent No. 5,422,097; 1449), Illum (U.S. Patent No. 5,690,954; 1449), Illum (U.S. Patent No. 5,707,644; 1449) and Kublik et al. (Eur. J. Pharm. Biopharm. 39: 192-196, 1993; 1449).

Igari et al. teach the delivery of compositions comprising ICAM-1 (column 5, line 4), chitosan, gelatin, microspheres, polymeric materials for nasal delivery (see entire document, including Abstract, Summary of the Invention, Description of the Preferred Embodiments, columns 7-12, particularly columns 9-10, for example)

Igari et al. differs from the claimed invention by not explicitly disclosing the ability of ICAM-1 to inhibit rhinovirus infections.

Greve et al. teach the use of the HRV receptor or ICAM-1 to inhibit rhinovirus attachment and infectivity, including providing ICAM-1 to those areas susceptible to infection by rhinovirus such as intranasal sprays (see entire document, including Summary of the Invention, Description of the Preferred Embodiments, column 4, paragraph 2, for example).

Greve et al. differs from the claimed invention by not disclosing providing the HRV receptor/ICAM-1 with a bioadhesive per se.

Igari et al. and Greve et al. do not disclose polymeric formulations wherein the ICAM-1 is in the particular claimed concentrations such as 0.1-5%, 0.2-2%, 0.2-5%, 1%-20% and 0.1-50% w/v.

Wegner teach delivering ICAM-derived antagonists, including controlled release preparations and polymeric materials (see entire document, including Detailed Description of the Preferred Embodiments, including Administration or the Compositions of the Present Invention on columns 15-16).

Gwaltney et al. teach the use of antiviral ICAM-1 (column 10) including preparation of such antiviral agents for intranasal delivery (see entire document, particularly Description of the Preferred Embodiments, including columns 11-12, overlapping paragraph).

Illum ('954), Illum ('644) and Kublik et al. teach various bioadhesive formulations encompassed by the claimed invention for drug delivery to the nasal cavity, as well as the various considerations of mixing said bioadhesive materials with a wide variety of active drugs to increase their bioavailability upon administration (see entire documents).

For example, Illum ('954) teaches that the bioadhesive formulations and delivery systems provide for greater bioavailability of the active drug and that certain formulations are due to the greater retention of the delivery system in the nasal cavity (for example, see column 4, paragraphs 1-4; column 6, paragraph 2; column 8, paragraphs 5-6). Also, Illum ('954) teaches various Examples of concentrations, including 0.5, 2, 4, and 5% w/v Rose bengal (see columns 7-8, overlapping paragraph).

In addition, Illum ('644) teaches that the amount of drug that can be carried by the microspheres is termed the loading capacity, which is determined by the physico-chemical properties of the drug molecule an in particular its size and affinity for the particle matrix (see column 6, paragraph 3). It is known that for many peptides and proteins the amount of drug substance to be administered for a resultant therapeutic effect will be of the order of a few micrograms or less.

Given the teaching of the prior art including the motivation and expectation of success in providing an antiviral effective amount ICAM-1 to the nasal cavity; it would have been obvious and expected that the various w/v concentrations encompassed by the claims would have been provided in inhibiting rhinovirus attachment and infectivity based on the needs of the patient and the nature of the infection by the ordinary artisan at the time the invention was made. The prior art teaches the various bioadhesive materials encompassed by the claimed invention for the purposes of increasing the bioavailability of active substances. Also, Illum ('954) teach an example of various concentrations of an active substance in polymeric bioadhesive materials that read on the claimed limitations, providing evidence that various concentrations of active ingredients would have been expected at the time the invention was made.

Also, it is noted that where the general condition of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 105 USPQ 233, 235, (CCPA 1955). See MPEP 2144.05.

Further, a particular parameter must first be recognized as a result-effective variable, a variable which achieves a recognized result, before the determination of the optimum or workable ranges of said variable might be characterized as routine experimentation. See In re Antoine, 195 USPQ 6 (CCPA 1977). See MPEP 2144.05.

Here, the prior art teaches providing ICAM-1 to combat rhinovirus infections, including intranasal administration and the use of polymeric compositions. In addition, the prior art teaches the various bioadhesive materials encompassed by the claimed invention, including their use with a wide variety of active drugs to achieve increase bioavailability of said active drugs. As pointed out above, Illum ('644) teaches that the amount of drug that can be carried by the microspheres is termed the loading capacity, which is determined by the physico-chemical properties of the drug molecule an in particular its size and affinity for the particle matrix (see column 6, paragraph 3). Therefore, the claimed limitations of formulations of ICAM-1 with bioadhesive materials were within the purview and expectation of the ordinary artisan at the time the invention was made to provide an increased bioavailability of an antiviral effective amount of ICAM-1 intra nasally.

One of ordinary skill in the art at the time the invention was made would have been motivated to provide ICAM-1 with a bioadhesive, including those encompassed by the claimed invention to increase the bioavailability of ICAM-1 in order to inhibit rhinovirus attachment and infectivity. From the teachings of the references, it was apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014..

Phillip Gambel, Ph.D.
Primary Examiner
Technology Center 1600
January 3, 2003